INSORB|25 is designed to capture the subcuticular dermis and secure the opposing sides together with an absorbable staple made of a polylactide-polyglycolide copolymer. The staples are placed parallel to the skin edge rather than perpendicular to it, as is the case with traditional external metal staples. To accomplish this feat, the stapler has a patented design that uses 2 needles to capture the dermal tissues and external arms that approximate to bring the edges together. In addition, to facilitate the correct placement of the stapler (and, in turn, the staples), the device is intended to be used with an INSORB®|1 forceps, similar to modified double Adson forceps. The entire process is meant to be performed by a single clinician.

In testing by the reviewer, the INSORB|25 subcuticular skin stapler worked as advertised. It was a little cumbersome at first, but with experience, the technique is easy to master and results in nicely approximated skin edges.

Unfortunately, the product has no clinical outcome data to support the company's implication that the product yields improved cosmetic results as compared with either metal staples or traditional subcuticular suturing. Although the absence of skin perforations from traditional metal staples is compelling, the INSORB|25 does deposit a larger total foreign-body load in the dermis than a comparable subcuticular suture would, and that is certainly more than would be present when compared with removable metal staples. How this foreign-body load affects wound healing needs to be determined in a randomized, clinical trial. Tellingly, most of the company's literature relies on white papers and random 1-week postoperative photographs. Until these data are available, the cosmetic results of the product—which is really all that matters—cannot be assessed.

Design/Functionality Score: 3

Value

Priced at $45, the INSORB|25 subcuticular skin stapler is significantly more costly than either a pack of suture or a traditional metal skin stapler, both of which are commodity items and can be purchased for less than $10. Even factoring in the cost of a staple remover (less than $5), the INSORB|25 represents a fairly expensive skin closure option. The company justifies the increased cost by pointing to the cost savings in operating room and anesthesia times, and in the "elimination of the need to remove metal staples postoperative."[2] Even from a truly lazy rounding doctor as the reviewer, who hates removing metal staples, this seems to be a stretch.

Value Score: 1

Summary

INSORB|25 subcuticular skin stapler is a cleverly designed, well-reasoned device. It is easy to use and yields an immediately pleasant-appearing skin closure. However, it is essentially untested in terms of its long-term (1 year +) cosmetic results, and it does add about $25 to each case. Until compelling cosmetic result data become available, the device does not seem worth the cost.

Overall Score: 2.5 ■

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Product: Alexis® O™ C-Section Retractor
Company: Applied Medical Resources Corporation
Retail Price: $375 per box of 5

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Evaluation

Design/Functionality: 4
Value: 1.5
Overall Score: 2.5

Background

In the United States, cesarean delivery has become one of the most frequently performed operations, with over 30% of births delivered abdominally. In addition to the numerous papers written to determine the cause of this rate increase, much attention has been focused on the surgical techniques of the procedure. In particular, the past 10 years have seen resurgence in the debate over exteriorization of the uterus for hysterotomy repair. Proponents of the exteriorization have extolled the ease with which the uterine incision is closed, whereas opponents have opined that the technique increases both infectious morbidity and postoperative pain. Muddying the waters further, a 2004 Cochrane Review concluded," [t]here is no evidence from this review to make definitive conclusions about which method of uterine closure [extra-abdominal versus intra-abdominal] offers greater advantages, if any. However, these results are based on too few and too small studies to detect differences

in rare, but severe, complications."[1] A more recent randomized study by Coutinho and colleagues[2] from Brazil, published in *Obstetrics & Gynecology* in March 2008, was able to demonstrate no difference in infection morbidity. Procedures were shorter with exteriorization, but there was less pain at 6 hours with in situ repairs. The extra-abdominal versus intra-abdominal debate appears reduced to surgeon preference. For those inclined towards in situ hysterotomy closures, exposure is an issue and, to this end, Applied Medical Resources Corporation (Rancho Santa Margarita, CA) offers the Alexis® O™ C-Section Retractor.

Design/Functionality

Alexis O C-Section Retractor is a disposable, single-use device that consists of a flexible polymer membrane formed into the shape of a cylinder. Attached to each end of the cylinder are 2 semirigid polymer rings. It is available in 2 sizes: large (for 9- to 14-cm incisions) and extra large (for 11- to 17-cm incisions). It is simple to set up and easy to use. After an abdominal incision is made, the Alexis O C-Section Retractor is placed in position through the incision with 1 ring inside the abdomen. The external ring is placed in traction and folded over itself until it contacts the abdomen. Once securely in place, the Alexis® wound retractor keeps the incision open during the procedure.[3] With the uterus exposed, a hysterotomy is then performed and the infant is delivered through the retractor.

In testing by the author, the device performed as intended. It provided excellent exposure through a Pfannenstiel incision and closing the uterus in situ was easier than without it. On the downside, delivering the infant through the ring was a bit more cumbersome than without it and did raise an eyebrow of concern about the device's use when difficult deliveries are encountered. The company claims the device provides wound "protection" in addition to hands-free retraction. Specifically, they claim the Alexis O C-Section Retractor "[s]ignificantly decreases wound infection." This claim is based on a nicely done Japanese study of 221 patients that demonstrated a statistically significant reduction in surgical site infections in patient randomized to retraction with the Alexis O C-Section retractor.[4] Unfortunately, the study was performed in patients undergoing colorectal surgery where perioperative infectious morbidity is about 25% to 40%, as compared with cesarean delivery, where the risk is closer to 5%.[5] This fact, when taken in conjunction with the failure of intra-abdominal uterine closure to demonstrate a reduction in infections, renders this possible benefit less significant.

Design/Functionality Score: 4

Alexis® O™ C-Section Retractor (Applied Medical Resources Corporation, Rancho Santa Margarita, CA). Photo courtesy of Applied Medical Resources Corporation.

Value

Priced at $75 per piece, the Alexis O C-Section Retractor is not cheap. For high-volume institutions such as Brigham and Women's Hospital, in which upwards of 3000 cesarean deliveries are performed a year, this could yield a $225,000 per year increase in expenses. This added cost would be reasonable if there were demonstrable counterbalancing savings, but there are none. Thus, this device seems like added cost for only a marginal benefit at best.

Value Score: 1.5

Summary

The Alexis O C-Section Retractor is the Alexis wound retractor repackaged to try to appeal to the growing cesarean delivery market. Although the Alexis wound retractor occupies a helpful niche in open abdominal surgery (particularly for minilaparotomies), Alexis O C-Section Retractor does not appear to add a lot to operative obstetrics. Even for those in situ hysterotomy repair diehards, the benefits do not seem to justify the cost.

Overall Score: 2.5 ■

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Dr. Greenberg reports no personal financial relationships with any of the companies whose products he reviews in this column.